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SERIAL NUMBER FILING DATE FIRST NAMED INVENTOR ATTORNEY DOCKET NO. 08/242,738 05/13/94 HUEBNER R EXAMINER 33M1/0222 BENNET K. LANGLOTZ **ART UNIT** PAPER NUMBER 4678 S.W. FLOWER PLACE PORTLAND, OR 97221 3309 DATE MAILED: 02/22/95 This is a communication from the examiner in charge of your application. COMMISSIONER OF PATENTS AND TRADEMARKS This application has been examined Responsive to communication filed on ______ This action is made final. A shortened statutory period for response to this action is set to expire ______ _ month(s), ____ _ days from the date of this letter. Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133 Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION: 1. Motice of References Cited by Examiner, PTO-892. 2. Notice of Draftsman's Patent Drawing Review, PTO-948. Notice of Art Cited by Applicant, PTO-1449. Notice of Informal Patent Application, PTO-152. 5. Information on How to Effect Drawing Changes, PTO-1474. Part II SUMMARY OF ACTION 1. Claims are pending in the application. are withdrawn from consideration. 2. Claims have been cancelled. 3. Ciaims 4. Claims 5. Claims are subject to restriction or election requirement. 7. This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes. 8. Formal drawings are required in response to this Office action. 9. The corrected or substitute drawings have been received on _ . Under 37 C.F.R. 1.84 these drawings are acceptable; not acceptable (see explanation or Notice of Draftsman's Patent Drawing Review, PTO-948). 10. The proposed additional or substitute sheet(s) of drawings, filed on _ examiner; disapproved by the examiner (see explanation). 11. The proposed drawing correction, filed ____ ____, has been approved; disapproved (see explanation). 12. Acknowledgement is made of the claim for priority under 35 U.S.C. 119. The certified copy has been received not been received been filed in parent application, serial no. _____; filed on _____ 13. Since this application apppears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213. 14. Other

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Restriction to one of the following inventions is required under 35 U.S.C. 121:

Group I. Claims 1-18, drawn to a humeral intramedullary nail, classified in Class 606, subclass 64.

Group II. Claims 19-22, drawn to a method of manufacturing a nail, classified in Class 72, subclass 369.

Group III. Claims 23-26, drawn to a method of implanting a humeral nail into a humerus, classified in Class 606, subclass 64.

The inventions are distinct, each from the other because of the following reasons:

Inventions II and I are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (M.P.E.P. § 806.05(f)). In the instant case the product made can be made by another and materially different process, such as machining the curvature into the nail rather than bending the nail.

Inventions III and I are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the

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apparatus as claimed can be used to practice another and materially different process. (M.P.E.P. § 806.05(e)). In this case the apparatus as claimed can be used to practice another and materially different process, such as being used in a fractured humerus without broken fragments.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Because these inventions are distinct for the reasons given above and the search required for Group I is not required for Group III, restriction for examination purposes as indicated is proper.

During a telephone conversation with Bennett Langlotz on 1-26-95 a provisional election was made with traverse to prosecute the invention of Group I, claims 1-18. Affirmation of this election must be made by applicant in responding to this Office action. Claims 19-26 are withdrawn from further consideration by the Examiner, 37 C.F.R. § 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least

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one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

The oath or declaration is defective. A new oath or declaration in compliance with 37 C.F.R. § 1.67(a) identifying this application by its Serial Number and filing date is required. See M.P.E.P. §§ 602.01 and 602.02.

The oath or declaration is defective because:

Non-initialed alterations have been made to the oath or declaration (see 37 C.F.R. \S \$ 1.52(c) and 1.57).

The drawings are objected to because:

Element 12 is not shown in figure 1 as indicated on page 2, line 17.

Element 24, referred to on page 2, line 25 and page 3, line 17, is not shown in the drawings.

Element 32, referred to on page 3, line 13 is not shown in the drawings.

In figure 1, there are two different elements each numbered "30".

Element 22 is not shown in figure 2 as indicated on page 3, line 18.

Correction is required.

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The disclosure is objected to because of the following informalities:

Element "26" in figure 1 is not discussed in the specification.

Appendices A-D should either be incorporated into the specification or removed from the file. There are provisions for appending computer programs of more than 11 pages in an application, but the examiner is aware of no provision for four additional figures to be appended.

Appropriate correction is required.

Claims 3, 7, 11 and 15-18 are rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 3, "at least two of the hole axes" is indefinite since the base claim merely requires two holes.

In claim 7, "less than 45 degrees" lacks antecedent basis in the specification.

In claim 11, "20-50%" lacks antecedent basis in the specification.

In claim 15, line 9, "the distal end" lacks antecedent basis in the claim.

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In claim 18, "alignment element" lacks antecedent basis in the specification.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this office action:

A person shall be entitled to a patent unless -(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 1-14 are rejected under 35 U.S.C. § 102(e) as being anticipated by Greene et al (5,248,313). Greene et al discloses an elongated tapered nail comprising an elongate body (12) with a curved shank (18), a butt portion (20) and a plurality of transverse holes (26,28,30). Regarding claim 3, see figure 3 of Greene et al. Regarding claim 4, see column 4 line 4. Regarding claim 9, note that the butt portion can be taken to include element 24 (24 and 30 are offset from the perpendicular). Regarding claim 10, see element 24. Regarding claim 11, note that 1.5 inches is 29% of 5.25 inches. Regarding claim 12, see element 14. Regarding claim 13, note the gentle five degree curve of Greene et al (see specification at page 4, lines 23-25).

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Claims 15-18 would be allowable if rewritten to overcome the rejection under 35 U.S.C. 112 and to include all of the limitations of the base claim and any intervening claims.

The prior art made of record and not relied upon is considered pertinent to the applicant's disclosure.

Zindrick et al discloses an elongate tapered nail with a curve having a plurality of angularly offset holes in a butt portion. Otte et al and Frigg disclose curved, tapered nails. Chapman et al discloses a nail with a butt portion hole (30) angularly offset approximately 30 degrees from the reference plane. Ender discloses a nail with angularly offset holes. Mouradian discloses a humeral nail.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Guy Tucker at telephone number (703) 308-3271. Examiner Tucker can normally be reached on Monday through Thursday from 6:30 AM to 5:00 PM, Eastern Time.

If attempts to reach the examiner by telephone are unsuccessful, examiner Tucker's supervisor, Steve Pellegrino, can be reached at (703) 308-0871. The fax number for Group 3300 is (703) 305-3590 or 3591.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group 3300 receptionist at (703) 308-0858.

Patent Examiner

Group 3300

January 27, 1995